QA-45
User & Service Manual

QA-45 Defibrillator and Transutaneous Pacemaker Analyzer

METRON

P/N 13060

Copyright © 2001 by METRON. All rights reserved.

METRON:

USA
1345 Monroe NW, Suite 255A
Grand Rapids, MI 49505
Phone: (+1) 888 863-8766
Fax: (+1) 616 454-3350
E-mail: support.us@metron-biomed.com

FRANCE
30, rue Paul Claudel
91000 Evry, France
Phone: (+33) 1 6078 8899
Fax: (+33) 1 6078 6839
E-mail: info@metron.fr

NORWAY
Travbaneveien 1
N-7044 Trondheim, Norway
Phone: (+47) 7382 8500
Fax: (+47) 7391 7009
E-mail: support@metron.no

Disclaimer

METRON provides this publication as is without warranty of any kind, either express or implied, including but not limited to the implied warranties of merchantability or fitness for any particular purpose. Further, METRON reserves the right to revise this publication and to make changes from time to time to the content hereof, without obligation to METRON or its local representatives to notify any person of such revision or changes. Some jurisdictions do not allow disclaimers of expressed or implied warranties in certain transactions; therefore, this statement may not apply to you.

Limited Warranty

METRON warrants that the QA-45 Defibrillator/Transcutaneous Pacemaker Analyzer will substantially conform to published specifications and to the documentation, provided that it is used for the purpose for which it was designed. METRON will, for a period of twelve (12) months from date of purchase, replace or repair any defective system, if the fault is due to a manufacturing defect. In no event will METRON or its local representatives be liable for direct, indirect, special, incidental, or consequential damages arising out of the use of or inability to use the QA-45 Defibrillator/Transcutaneous Pacemaker Analyzer, even if advised of the possibility of such damages. METRON or its local representatives are not responsible for any costs, loss of profits, loss of data, or claims by third parties due to use of, or inability to use the QA-45 Defibrillator/Transcutaneous Pacemaker Analyzer. Neither METRON nor its local representatives will accept, nor be bound by any other form of guarantee concerning the QA-45 Defibrillator/Transcutaneous Pacemaker Analyzer other than this guarantee. Some jurisdictions do not allow disclaimers of expressed or implied warranties in certain transactions; therefore, this statement may not apply to you.

Table of Contents

1. Introduction.....1

1.1 QA-45 Features 1
1.2 Defibrillator Analyzer Specifications.....2
1.3 Transcutaneous PPacemaker Analyzer Specifications.....5
1.4 General Information.....6

2. Installation.....1

2.1 Receipt, Inspection and Return.....1
2.2 Setup.....1
2.3 Power 2
2.4 Internal Paddles.....4
2.5 Special Contacts.....4
2.6 PRO-Soft QA-40M/45.....4

3. Operating QA-45.....1

3.1 Control Switches and Connections.....1
3.2 QA-45 Menu and Function Keys.....3
3.3 Menu and Messages: Defibrillator Mode.....4
3.4 Menu and Messages: Transcutaneous Pacemaker Mode.....6
3.5 Test Result Printouts.....8

4. Defibrillator Mode Testing.....1

4.1 Introduction.....1
4.2 Test Preparation.....1
4.3 Energy Test 3
4.4 Cardioversion Test.....4
4.5 Maximum Energy Charging Time Test.....6
4.6 Shock Advisory Algorithm Test.....7

5. Transcutaneous Pacemaker Mode Testing.....1

5.1 Introduction.....1
5.2 Testing Preparation 1
5.3 Demand Sensitivity Test.....3
5.4 Refractory Period Test.....5

6. Control and Calibration.....1

6.1 Required Test Equipment.....1
6.2 Preparation.....1
6.3 References.....1
6.4 Test.....1

7. Component Functions and Parts.....1

7.1 Theory of Operation 1
7.2 Processor Board.....1
7.3 Sensor Board.....3
7.4 ECG Signal Distribu- tion Board.....4
7.5 Pacer Unit.....5
7.6 Component Parts 6

Appendix A – Diagrams A-1

Appendix B – Error Report Form.....B-1

Appendix C – Improvement Suggestion Form.....C-1

Manual Revision Record

This record page is for recording revisions to your *QA-45 User & Service Manual* that have been published by METRON AS or its authorized representatives. We recommend that only the management or facility representative authorized to process changes and revisions to publications:

- make the pen changes or insert the revised pages;
- ensure that obsolete pages are withdrawn and either disposed of immediately, or marked as superseded and placed in a superseded document file, and;
- enter the information below reflecting that the revisions have been entered.

Rev No	Date Entered	Reason	Signature of Person Entering Change
2.60-1	4-30-01	General update	

This page intentionally left blank.

1. Introduction

This chapter describes the Metron's QA-45 Defibrillator / Transcutaneous Pacemaker Analyzer features and specifications.

1.1 QA-45 Features

The QA-45 Analyzer is a precision instrument for testing defibrillators and transcutaneous pacemakers, and is designed to be used by trained service technicians.

The defibrillator function of the QA-45 measures the energy output, and ensures that the defibrillator complies with specified requirements. QA-45 has a built-in load resistance of 50 ohm, which roughly corresponds to the impedance of the human body. The defibrillator pads are placed on the QA-45 contact plates. Thus, the defibrillator is connected through the load resistance. When the defibrillator is discharged, QA-45 calculates and displays the energy delivered.

In the pacer function the QA-45 tests all types of transthoracic pacemakers. The testing is menu driven, and simple to operate. QA-45 measures and displays a pulse's amplitude, rate, energy and width. It also conducts demand sensitivity tests, measuring and displaying refractory periods, and immunity tests, which determine the pacemaker's susceptibility to 50/60 Hz interference.

1.2 Defibrillator Analyzer Specifications

1. **Energy Output Measurement**

High Range

Voltage	<5000 volts
Maximum current	120 amperes
Maximum energy	1000 Joules
Accuracy	± 2 % of reading for >100 Joules ± 2 Joule of reading for <100 Joules
Trigger level	100 volts
Playback amplitude	1 mV/1000 V Lead I
Test pulse	100 + 4 Joules

Low Range

Voltage	<1000 volts
Maximum current	24 amperes
Maximum energy	50 Joules
Accuracy	± 2% of reading for >20 Joules ± 2 Joule of reading for <20 Joules
Trigger level	20 volts
Playback amplitude	1 mV/200 V Lead I
Test pulse	Approx. 4 Joules
Load Resistance	50 ohms ± 1%, non-inductive (<1 μH)
Display Resolution	0.1 Joules
Measurement Time Window	100 ms
Absolute Max. Peak Voltage	6000 volts
Pulse Width	100 ms
Cardioversion	Measured time delay ± 2 ms

Oscilloscope Output

High measure range	1000:1 amplitude-attenuated
Low measure range	200:1 amplitude-attenuated

Waveform Storage And Playback

Discharge can be viewed via ECG outputs and paddles.

Output: 200:1 Time Base expansion.

Sync Time Measurements

Timing window	Starts - 40 ms at each R-wave peak.
Test waveforms	All waveform simulations available.
Delay time accuracy	± 1 ms

Charge Time Measurement

From 0.1 seconds to 99.9 seconds.

2. **ECG Wave**

ECG General

Lead configuration	12-lead simulation. RL, RA, LA, LL, V1-6	
Output impedance	Limb leads	1000 ohms to RL
	V Leads	1000 ohms to RL

All other signals are in relative proportion to Lead amplitude as follows: The amplitudes are shown for a Lead I amplitude by 1 mV:

Lead I	1.0 mV (LA - RA)
Lead II	1.5 mV (LL - RA)
Lead III	0.5 mV (LL - LA)
V Lead	1.5 mV (V - 1/3 (LL+LA+RA))

High Level Output (ECG Jack)

1/4" standard phone-jack with an amplitude of 1V/mV of low level Lead II signal

Defibrillator Contact Plates

Same amplitude as Lead I low level ECG.

1 mV between contact surfaces.

Playback

200 to 1 time-base expansion of defibrillator pulse by playback to ECG Leads

Manual ECG Performance Test

DC Pulse	4 seconds 1.0 mV
Square wave	2 Hz 1.0 mV p-p biphasic
Triangular wave	2 Hz 1.0 mV
Sine	0.1, 0.2, 0.5, 10, 40, 50, 60, and 100 Hz
Amplitude	0.5, 1.0, 1.5, 2.0 mV (Lead II)
Accuracy	± 5 % (Lead II 1.0 mV)

ECG Performance Test

Gain/Damping	2 Hz square wave
Frequency Response	
Low Frequency	4 second DC pulse
Band Pass	10 Hz sine
Monitor	-3dB point: 40 Hz sine
Power Line Notch Filter	50 Hz sine
Linearity	2 Hz triangle wave

Normal Sinus

Rates	30, 60, 80, 120, 180, 240 and 300 BPM.
Accuracy	±1% of selection
Amplitudes	0.5, 1.0, 1.5 and 2.0 mV (Lead II)
Accuracy	±5 % (Lead II 1.0 mV)

Automatic ECG Rate Test

Arrhythmia Selections

vfib	Ventricular Fibrillation
afib	Atrial Fibrillation

blk II	Second degree A-V block
RBBB	Right Bundle Branch Block
PAC	Premature Atrial Contraction
PVC_E	Early PVC
PVC_STD	PVC
PVCRonT	R on T PVC
mfPVC	Multifocal PVC
bigeminy	Bigeminy
run5PVC	Bigeminy Run of 5 PVCs
vtach	Ventricular Tachycardia

Shock Advisory Test Algorithms

ASYS	Asystole
SVTa_90	Supraventricular Tachycardia
PVT_140	
PVT_ 160	
MVT_140	
MVT_160	
CVF	Course Ventricular Fibrillation
FVF	Fine Ventricular Fibrillation

1.3 Transcutaneous Pacemaker Analyzer—Specifications

1. TEST LOAD RANGE

50 to 2300 ohms in step of:

50 ohm up to 200 ohms

100 ohm from 200 up to 2300 ohms

Accuracy	50 - 1300 ohm ±1%
	1400 - 2300 ohm ±1.5 %

Oscilloscope Output

50 - 150 ohm	10.24:1 amplitude attenuation
200 - 500 ohm	41:1 amplitude attenuation
600 - 2300 ohm	164:1 amplitude attenuation

2. PULSE MEASUREMENTS

Amplitude	4 to 300 mA (100 ohm load)
Accuracy	±5 % or ±0.5 mA
Max. Amplitude	300 mA all loads
Rate	30 to 800 ppm
Accuracy	±1% or 2 ppm
Pulse width	0.6 to 80 ms
Accuracy	±1% or ±0.3 ms

3. DEMAND SENSITIVITY TEST

Waveforms	Square(SQR), Triangle(TRI), and Havemine (SSQ)
ECG output	Amplitude 0 - 4 mV
	Resolution 40 μV
Pacer input (Load depended)	
Amplitude (50 ohm)	0 10 mV
Resolution (50 ohm)	40 μV
Amplitude: (≥500 ohm)	0 - 100 mV
Resolution: (≥500 ohm)	1 mV
Defib. Pads Amplitude	0 10 mV
Resolution	0.1 mV
Waveform width	10, 25, 40, 100 and 200 ms
Pacer rate	30 to 120 ppm

Immunity Test

50/60 Hz Interference Signal

ECG output	0 - 4 mV peak in steps of 0.4 mV
Pacer input	(Load dependent)
	0 - 10 mV peak in steps of 1 mV (50 ohm)
	0 - 100 mV peak in steps of 10 mV (≥500 ohm)
Defibrillator pads	0 - 10 mV peak in steps of 1 mV

4. Refractory Period Measurement

20 to 500 ms (both Pacing and Sensing) Accuracy: ±2 ms

1.4 General Information

Temperature Requirements

+15°C to +35°C when operating

0°C to +50°C in storage

Display

Type	LCD graphic display
Alphanumeric format	6 lines, 40 characters

Data Input/ Output (2)	Parallel printer port (1); Bi-directional RS -232C (1) for Computer control
Power	2 x 9 volt alkaline Battery Duracell® MN1604 (or equivalent) for 20 -25 operational hours, or 240 VAC (Battery Eliminator), 115 VAC for US.

Mechanical Specifications

Housing	High impact plastic case	
Height	9.8 cm	3.9 in.
Width	24.8 cm	9.8 in.
Depth	28.0 cm	11.0 in.
Weight	2.06 kg (with battery)	4.5 lbs

Recommended Printer	HP DeskJet 500C / 550C and Canon BJ -10SX.

Standard Accessories

110 V or 220 V AC Adapter	(P/N 17021)
Internal paddle-contact adapter	(P/N 13403)
Ground contact adapter	(P/N 13404)
Snap-to-banana adapters (10 pk)	(P/N 17023)
User and Service Manual QA-45	(P/N 13060)

Additional Accessories

Defib. paddle adapter (specify defibrillator type)	(P/N 13410)
Pacemaker external load cable (specify type pacemaker type}	(P/N 13415)
Carrying case	(P/N 13422)
Carrying case, ext. printer	(P/N 10500)
PRO-Soft QA-40M/45 software	(P/N 13600)
PRO-Soft QA-40M/45 DEMO	(P/N 13601)
User Manual PRO-Soft QA-40M/45	(P/N 13605)

Storage

Store in the carrying case in dry surroundings within the temperature range specified, without battery. There are no other storage requirements.

Periodic Inspection

The unit should be calibrated every 12 months.

2. Installation

This chapter explains unpacking, receipt inspection and claims, and the general procedures for QA-45 setup.

2.1 Receipt, Inspection and Return

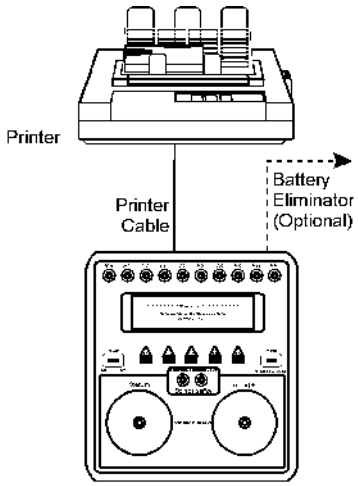
1. Inspect the outer box for damage.
2. Carefully unpack all items from the box and check to see that you have the following items:
   - QA-45 Defibrillator/Transcutaneous Pacemaker Analyzer (PN 17020)
   - 110 V or 220 V AC Adapter (P/N 17021)
   - Internal paddle-contact adapter (P/N 13403)
   - Ground contact adapter (P/N 13404)
   - 10 pack, Snap-to-banana adapter (P/N 17023)
   - *QA-45 User and Service manual* (P/N 13060)
3. If you note physical damage, or if the unit fails to function according to specification, inform the supplier immediately. When METRON AS or the company's representative, is informed, measures will be taken to either repair the unit or dispatch a replacement. The customer will not have to wait for a claim to be investigated by the supplier. The customer should place a new purchase order to ensure delivery.
4. When returning an instrument to METRON AS, or the company representative, fill out the address label, describe what is wrong with the instrument, and provide the model and serial numbers. If possible, use the original packaging material for return shipping. Otherwise, repack the unit using:
   - a reinforced cardboard box, strong enough to carry the weight of the unit.
   - at least 5 cm of shock-absorbing material around the unit.
   - nonabrasive dust-free material for the other parts.

   Repack the unit in a manner to ensure that it cannot shift in the box during shipment.

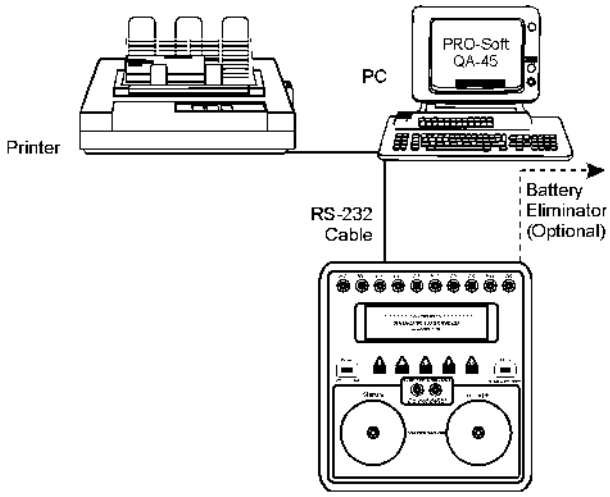
   METRON's product warranty is on page ii of this manual. The warranty does not cover freight charges. C.O.D. will not be accepted without authorization from METRON A.S or its representative.

2.2 Setup

1. Equipment connection is as shown in the typical setup below.



2. If PRO-Soft QA-40M/45 is being used, attach an RS-232 (null modem/data transfer configured) cable to the 9-pin D-sub outlet port located at the rear of the QA-45. Do not attach the printer cable to the QA-45. *See below*. However, if you are not using PRO-Soft QA-40M/45, and are sending directly to a printer for printouts, attach the printer cable to the 25-pin outlet port.



NOTE
Some RS-232C cables are missing the connection between the seventh and the eighth wires in the cable. The cable may still be called NULL-modem, but it will not work with the QA-45. Refer to the PRO-Soft QA-40M/45 Users Manual for more information.

2.3 Power

1. **Main On/Off Switch.** QA-45 should remain off for at least 5 seconds before switching on again, in order to allow the test circuits to discharge fully.
2. **Low Battery Power.** If battery power falls below 6.9 volts (± 0.3 volts), the display will show 'Change battery, and reset system'. This means that the battery should either be replaced or the instrument should be connected to a battery eliminator. The

main switch has to be switched off and then on again in order to use the instrument.

3. **Changing Batteries.** Open the compartments in the base of the instrument, replace the old batteries with new ones, and close the compartment covers. Use 9 volt alkaline batteries (Duracell MN1604 or similar).

NOTE
Do not use mercury, air or carbon-zinc batteries.

4. **Battery Eliminator**

METRON's AC Adapter plug-in power supply transformer allows you to use the QA-45 anywhere a standard electrical outlet is available. To attach the AC Adapter insert the adapter's small connector into the micro jack labeled "Batt. Elim. 9V DC" on the right rear of the unit. Plug the large connector into the nearest standard electrical outlet.

NOTE
Remove the batteries and disconnect the AC Adapter if you do not intend to use the QA-45 for an extended period of time.

2.4 Internal Paddles

To be able to test defibrillators with internal paddles, an internal paddle adapter has to be used. These contacts have a banana plug that is attached to the standard paddle contact, and which is protected by a plastic insulation washer.

2.5 Special Contacts

Certain defibrillators (automatic models and those with pacer options) have special contacts that are fastened to the electrodes attached to the patient. Metron AS has special adapters to suit the majority of these defibrillators. These are available as accessories. They are more or less the same as the internal pad adapter except that they have a special adapter on the top, which matches the contact on the defibrillator.

Defibrillator paddle adapter (specify defibrillator type): (P/N 13410)

Pacemaker external load cable (specify type pacemaker type): (P/N 13415)

2.6 PRO-Soft QA-40M/45

PRO-Soft QA-40M/45 is a front-end test automation and presentation tool for METRON's QA-40M/45 Defibrillator/Transcutaneous Pacemaker Analyzer. It allows you to conduct the same tests, but by remote control via an IBM-compatible PC/XT with MS Windows (Version 3.1 or later). Additionally, the program has additional features to enhance your defibrillator and pacemaker maintenance.

Each of the QA-40M/45 tests can be run independently from PRO-Soft in the "Manual" test mode. Results are shown on the PC screen during testing, and the user is prompted to set the tested equipment accordingly. At the conclusion of tests, the user may print a report, store the test and results on disk, or both. Combinations of tests can be created and stored as "Test Sequences." The program maintains a library of these sequences. In this way you can store and retrieve sequences that are appropriate for each kind of equipment being tested at your facility.

Sequences can then be used independently, or can be attached to a checklist, written procedure, and equipment data in the form of a test "Protocol." The equipment data can be entered manually into the protocol, or it may be retrieved by PRO-Soft from database software or other equipment files. Protocols can be created easily for each defibrillator or transcutaneous pacemaker in your inventory, and stored for use. Test protocols with results can be printed, or

NOTE
PRO-Soft QA-40M/45 has its own user manual, which contains all the information concerning the program. If you order a demonstration version of the program you also receive the manual.

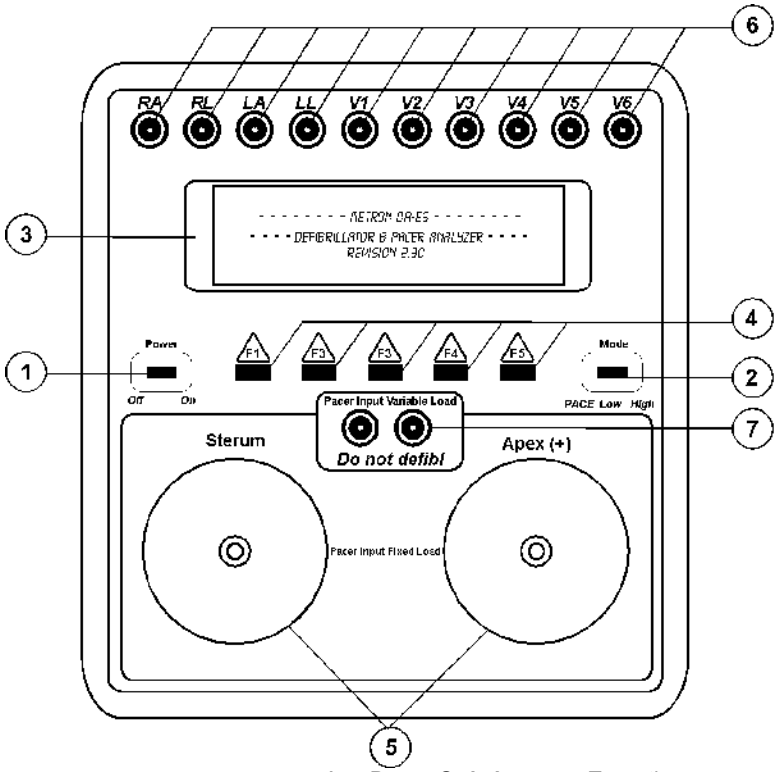
stored on disk, and the results of testing can be sent back to the equipment database to close a work order and update the service history.

3. Operating QA-45

This chapter explains the operating controls, switches and menus of the QA-45, details how to use them in testing , and provides general information on printouts and operator maintenance.

3.1 Control Switches and Connections

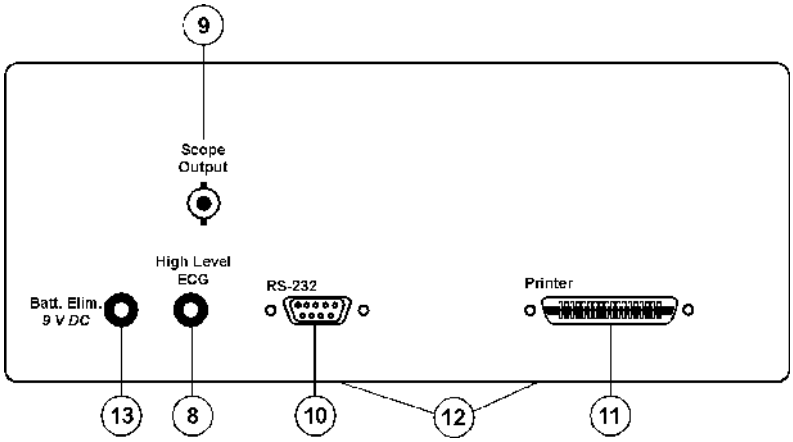
Top Panel



1.	**Power Switch**	Turns the power on and off.
2.	**Mode Switch**	Switches between PACE and Low / High ranges of defibrillator energy.
3	**LCD Display**	Shows messages, test results and function menus.
4	**Function Keys**	FI - F5 are used to select the functions shown on the bottom line of the LCD display, i.e., for selecting the function that is directly above the key.
5.	**Contact Surfaces**	The defibrillator's paddles are placed on these so that the discharged energy passes through the instrument in defib. mode and that the pacer signal passes through the instrument with a fixed 50 ohm load in the PACE mode.

6.	**Low Level ECG Connectors**	10 color-coded 4 mm safety terminals with snap-to-banana adapters.
7.	**Pacer Input Connectors**	The pacer output cables are connected to these so that the pacer signal passes through the instrument with a variable load selectable from 50 to 2300 ohms.

Rear Panel



8.	**High Level ECG Jack**	1/4" standard phone-jack for amplitude of 1 V/mV of low level Lead 1 signal.
9.	**Oscilloscope Output**	BNC-contact for attenuated signal in real time.
10.	**RS-232 Serial Port**	9-pin D-sub
11.	**Printer Outlet Port**	14-25 pin D-sub
12.	**Location of Batteries**	2 compartments in the base of the instrument can be opened to replace the batteries.
13.	**Battery Eliminator Socket**	Battery contact for connecting 9V 100 mA battery eliminator.

3.2 QA-45 Menu and Function Keys

The QA-45 uses display and programmable function keys to provide flexibility and control over the operations. The upper part of the screen displays messages, status and results. The menu bar is at the bottom of the display. The function keys are numbered from Fl to F5.

A function is selected by pressing the key located directly under the Menu Item displayed in the menu bar. A menu unit is written in capital letters.

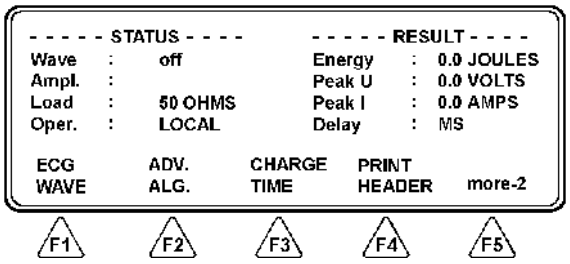
The menu comprises three pages. The next pages of the menu are selected by pressing **more-2**, **more-3** or **more-1**.

3.3 Menu and Messages: Defibrillator Mode

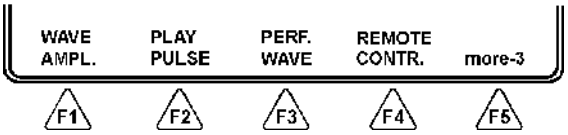
1. **Startup Screen**. The following screen will be displayed for 2 seconds after the QA-45 has been switched on.

2. **Main Menu**

   a. Main Menu Bar (Page 1) - Mode switch in Low or High position.

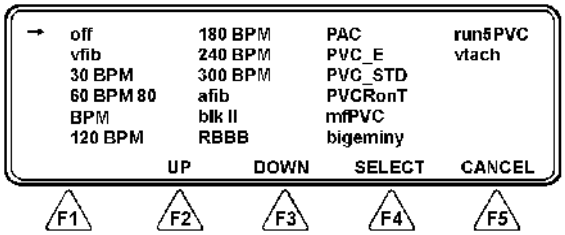


   b. Second Menu Bar (Page 2)



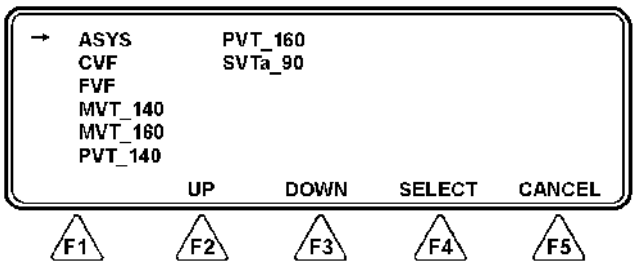
   c. Third Menu Bar (Page 3)

3. **ECG WAVE (F1)**



Choose desired wave by pressing **UP (F2)** or **DOWN (F3)**. Save this under 'Wave" in the STATUS field by pressing **SELECT (F4)**. Press **CANCEL (F5)** to cancel selection.

4. **ADV. ALG. (Advisory Algorithms) (F2)**.

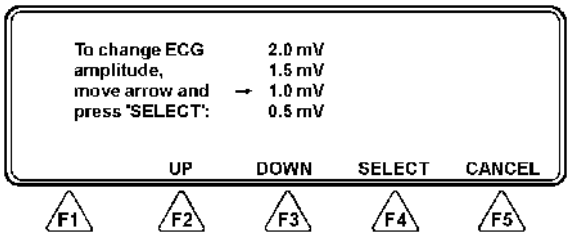


These ECG algorithms are meant to test the analysis and prompting feature of automatic and semi-automatic defibrillators. Choose desired selection by pressing **UP (F2)** or **DOWN (F3)**. Save this under 'Wave" in the STATUS field by pressing **SELECT (F4)**. Press **CANCEL (F5)** to cancel selection.

5. **CHARGE TIME (F3).** Used to test the battery and charging capacitor in the defibrillator. It changes the text 'Delay' to 'Chrg T' in the RESULT field in the main menu.

6. **PRINT HEADER (F4).** Automatically writes a heading for the new test protocol.

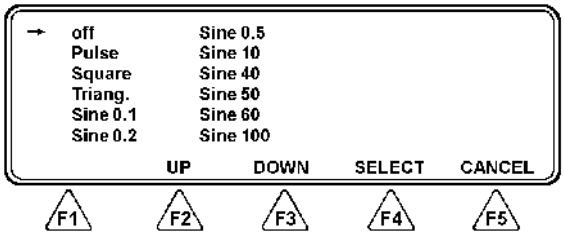
7. **WAVE AMPL. (Wave Amplitude) (F1).**



Choose desired amplitude by pressing **UP (F2)** or **DOWN (F3)**. Save this under 'Ampl" in the STATUS field by pressing **SELECT (F4)**. Press **CANCEL (F5)** to cancel selection.

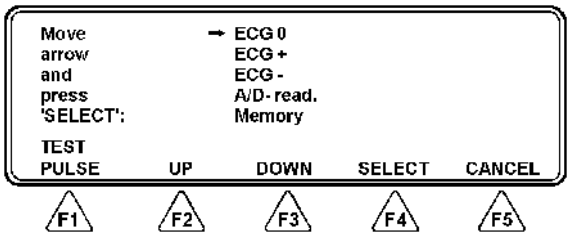
8. **PLAY PULSE (F2)** enables playback of the last discharge.

9. **PERF. WAVE (Performance ECG) (F3).**



Choose desired wave by pressing **UP (F2)** or **DOWN (F3)**. Save this under 'Wave" in the STATUS field by pressing **SELECT (F4)**. Press **CANCEL (F5)** to cancel selection.

10. **SYSTEM TEST (F1) .**



Choose a test variant by pressing **UP (F2)** or **DOWN (F3) or TEST PULSE (F1)**. Press **CANCEL (F5)** to cancel selection. For 'ECG0', 'ECG+' and 'ECG-' see Chapter 6, Control and Calibration. For 'A/D-read', see paragraph 7.3.7, page 7-5. Memory' is for factory testing. Also, see paragraph 4.3.5, page 4-3.

Note

QA-40M has an internally generated test pulse. The control pulse is set at 1.2 Joules in the Low range and 28.5 Joules in the High range. The test pulse is not a calibration pulse, and should not be used as an indication of the general accuracy of the instrument. The test pulse is a good control for testing functions.

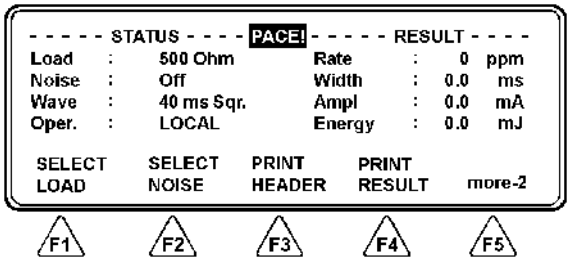
11. **REMOTE CONTR. (Remote Control) (F4)** enables communication with a PC with test automation software. Required software: PRO-Soft QA-40/45.

3.4 Menu and Messages: Transcutaneous Pacemaker Mode

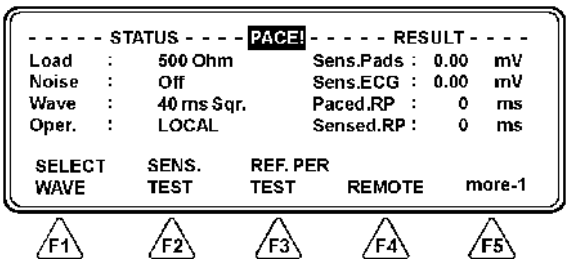
1. **Startup Screen**. The following screen will be displayed for 2 seconds after the QA-45 has been switched on.

2. **Main Menu**

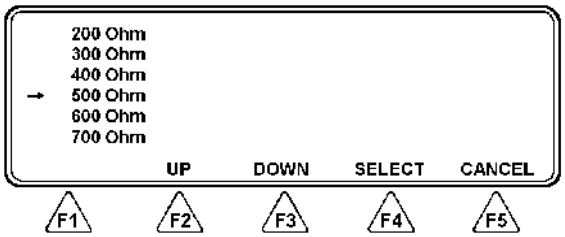
   a. Main Menu Bar (Page 1) - Mode switch in PACE position.



b. Second Menu Bar (Page 2)

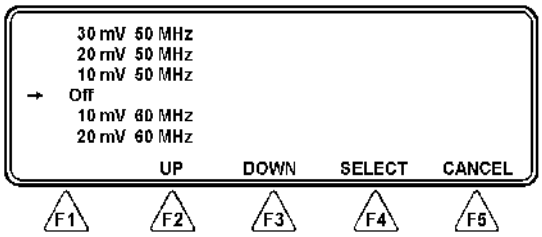


3. **SELECT LOAD (F1)**



Choose desired PACER load by pressing **UP (F2) or DOWN (F3)** and then **SELECT (F4)**. Press **CANCEL (F5)** to cancel selection.

4. **SELECT NOISE (F2)**

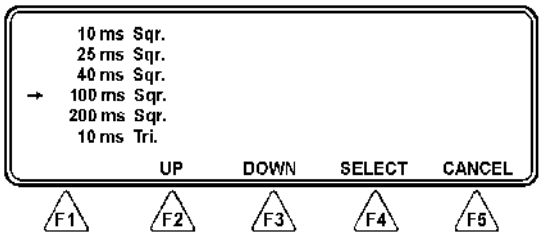


Choose desired noise for the immunity test by **UP (F2) or DOWN (F3)** and then **SELECT (F4)**. Press **CANCEL (F5)** to cancel selection.

5. **PRINT HEADER (F3).** Automatically writes a heading for the new test protocol.

6. **PRINT RESULT (F3).** Prints the results of measurements.

7. **SELECT WAVE (F2)**



Choose desired waveform for the sensitivity test by pressing **UP (F2) or DOWN (F3)** and then **SELECT (F4)**. Press **CANCEL (F5)** to cancel selection.

8. **SENS. TEST (Sensitivity Test) (F2).** Sensitivity is the QRS minimum amplitude (mV) required to cause the pacemaker to operate in the demand mode. This waveform is delayed from the pacer pulse so that it is outside the pacing refractory period. See 'Sensitivity Measurements' in Chapter 5.

9. **REF. PER TEST (F3).** Used to test time interval (ms) if the pacemaker is insensitive to any external inputs, the maximum time interval after the generation of a pacer pulse and maximum time interval after a QRS wave. See 'Pacing Refractory Period' and 'Sensing Refractory Period' in Chapter 5.

10. **REMOTE (Remote Control) (F4)** enables communication with a PC with test automation software. Required software: PRO-Soft QA-40/45.

3.5 Test Result Printouts

1. **Defibrillator Mode.** QA-45 automatically prints out the test results, via the printer output, after each discharge generated. Select **PRINT HEADER (F4)** if you want to print out a page with a new header.

2. **Pace Mode.** QA-45 prints out the test results, after the measurements, when you press **PRINT RESULT (F4)** in the Main menu.

This page intentionally left blank.

4. Defibrillator Mode Testing

This chapter describes QA-45 defibrillator mode testing.

4.1 Introduction

The defibrillator function of the QA-45 measures the energy output, and ensures that the defibrillator complies with specified requirements. QA-45 has a built-in load resistance of 50 ohm, which roughly corresponds to the impedance of the human body. The defibrillator pads are placed on the QA-45 contact plates. Thus, the defibrillator is connected through the load resistance. When the defibrillator is discharged, QA-45 will calculate and display the energy delivered.

Defibrillator energy is defined as an integral of the moment of the discharged energy from the defibrillator. The energy is equal to the square of the voltage, divided by the load resistance.

$$E = \int p\,dt = \int V^2 / R\,dt = \int V^2\,dt / R$$

QA-45 measures and records the voltage pulse every 100 µs, 1000 times, for a total time of 100 ms. The squares of the voltages are then summed, multiplied by 100 µs, and divided by the load resistance, 50 ohms.

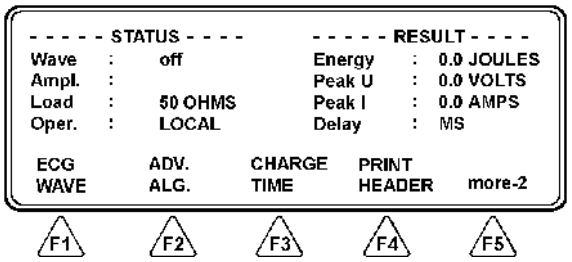
$$E = \sum_{0}^{1000} (V^2) \bullet dt / R = \sum_{0}^{1000} (V^2) \bullet 100\ \mu s / 50\ ohms$$

The unit for energy is 'joule', which is equal to Ws (Watt second).

4.2 Test Preparation

1. If checking ECG monitoring, prompting, or triggering from the ECG, connect the low level or high level ECG connectors to the ten 4 mm AHA color-coded safety terminals or standard phone jack, as appropriate.
2. Switch the QA-45 on. The following will be displayed in the LCD display for about two seconds:

3. The following main menu will then appear. It will show LOCAL, indicating that the testing is not remotely controlled by PRO-Soft QA-40M/45 test automation software.


- - - - - STATUS - - - -
Wave : off
Ampl. :
Load : 50 OHMS
Oper. : LOCAL
- - - - - RESULT - - - -
Energy : 0.0 JOULES
Peak U : 0.0 VOLTS
Peak I : 0.0 AMPS
Delay : MS
ECG WAVE
ADV. ALG.
CHARGE TIME
PRINT HEADER
more-2
F1
F2
F3
F4
F5

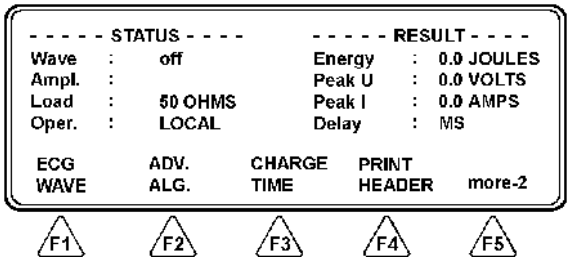
4.3 Energy Test

1. Select a suitable energy range using the mode switch.
   - Use the HIGH range for normal adult testing.
   - Use the LOW range for low energy testing, where the energy does not exceed 50 Joule and the peak voltage does not exceed 1200 volts.
2. Securely place the defibrillator paddles on the QA-45 contact plates, and discharge the defibrillator. The APEX (+) pad should be connected to the right-hand plate, and the STERNUM pad to the left plate. This ensures correct signal polarity for the oscilloscope output. A reversal of this configuration will not damage the QA-45, nor will it give incorrect energy readings. However, the polarity of the oscilloscope output will simply be reversed. The discharge from the defibrillator is transferred to the QA-45's load resistance.

Note
If the maximum voltage for a selected range is exceeded, the LCD display will show 'WARNING! Overload'

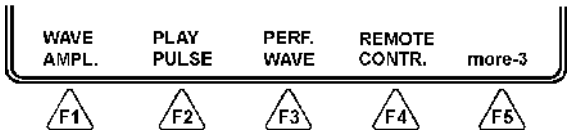
3. QA-45 calculates the energy delivered over the load resistance and displays the result in joules under RESULT. See below:

APEX (+) pad → right plate
STERNUM pad → left plate

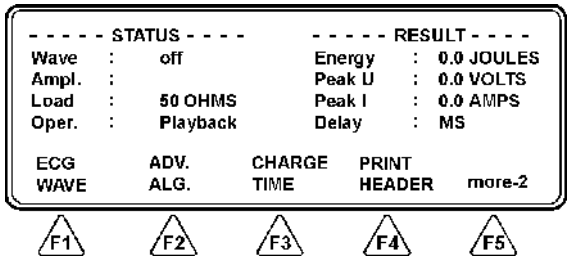


QA-45 also shows the energy measured, the maximum voltage and the maximum current in the energy wave. Following the discharge from the defibrillator, QA-45 shows a playback of the wave from the ECG output. A new pulse can be generated when the LCD display shows 'LOCAL'.

4. Following a discharge from the defibrillator, the instrument shows a playback of the wave from the ECG output. The display will thus be in playback mode. When this is shown in one line, QA-45 automatically prints out the result.
5. The discharged pulse can be repeated. To do this press **more-2 (F5)** to advance to page 2 of the main menu.



Press **PLAY PULSE (F2)**. The display will show 'Oper: Playback,' and displays the result in joules under RESULT.

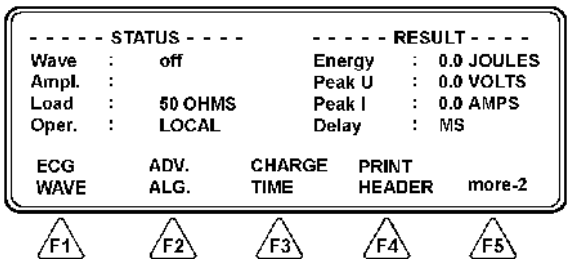


Following playback, the apparatus is ready to receive a new discharge from the defibrillator. The display will show 'LOCAL'.

6. When testing automatic defibrillators, it is quite common to have to select 'vfib' from the ECG menu 'ECG WAVE' for the 'ventricular fibrillation' wave. Automatic defibrillators typically do not fire without seeing 'v-fib'.

4.4 Cardioversion Test

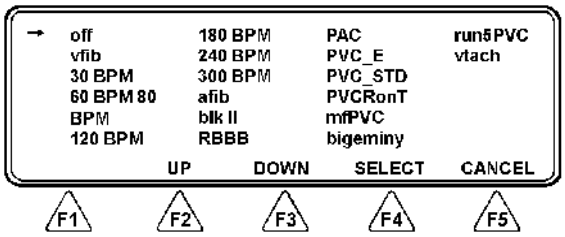
1. Select **ECG WAVE (F1)** from the main menu.



2. The ECG Wave menu opens. QA-45 includes the following ECG wave selection for cardioversion tests, or for the testing of electrocardiograph monitors.

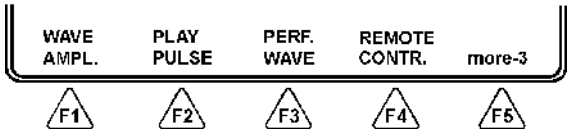
Normal Sine Rates: 30, 60, 80, 120, 180, 240 and 300 BPM.
ECG Arrhythmia types as follows:

vfib	Ventricular Fibrillation
afib	Atrial Fibrillation
blk II	Second degree A-V block
RBBB	Right Bundle Branch Block
PAC	Premature Atrial Contraction
PVC_E	Early PVC
PVC_STD	PVC
PVCRonT	R on T PVC
mfPVC	Multifocal PVC
bigeminy	Bigeminy
run5PVC	Bigeminy Run of 5 PVCs
vtach	Ventricular Tachycardia

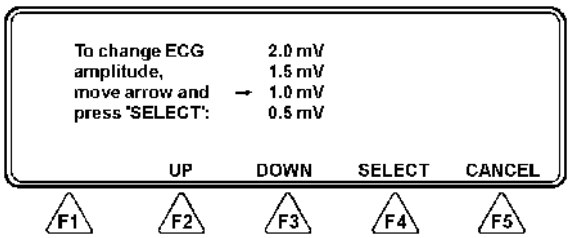


Select a desired wave by pressing **UP (F2) or DOWN (F3)**. Save this under 'Wave" in the STATUS field by pressing **SELECT (F4)**. Press **CANCEL (F5)** to cancel selection.

3. QA-45 includes the following ECG wave amplitude options: 0.5 mV, 1.0 mV, 1.5 mV and 2.0 mV. To change wave amplitude select **more-2** on the main menu. Select **WAVE AMPL. (F1)**.



The Wave Amplitude Menu appears:



APEX (+) pad → right plate
STERNUM pad → left plate

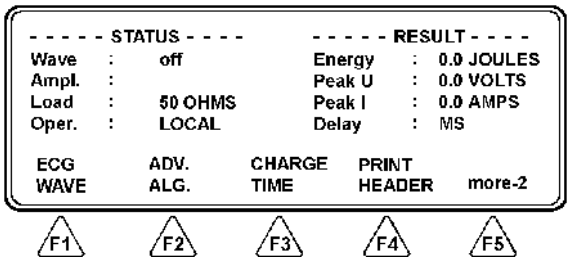
Select the desired amplitude by pressing **UP (F2) or DOWN (F3)**. Save this under 'Ampl" in the STATUS field by pressing **SELECT (F4)**. Press **CANCEL (F5)** to cancel selection.

4. Set the defibrillator to synchronized cardioversion mode. Discharge the defibrillator over the instrument's load resistance.
5. QA-45 measures the time delay in milliseconds (ms) between the top of the 'R' wave and the discharging of the defibrillator pulse. This delay will be shown in the LCD display as: 'Delay: xxx ms'.

   QA-45 also shows the energy measured, the maximum voltage and the maximum current in the energy wave. Following the discharge from the defibrillator, QA-45 shows a playback of the wave from the ECG output. A new pulse can be generated when the LCD display shows 'LOCAL'.

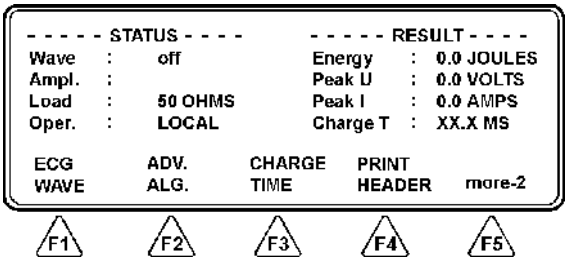
4.5 Maximum Energy Charging Time Test

1. The charge time function is used to test the battery and the charging capacitor in the defibrillator.
2. Set the defibrillator to maximum energy.
3. Securely place the defibrillator paddles on the QA-45 contact plates, and discharge the defibrillator. The APEX (+) pad should be connected to the right-hand plate, and the STERNUM pad to the left plate. This ensures correct signal polarity for the oscilloscope output. A reversal of this configuration will not damage the QA-45, nor will it give incorrect energy readings. However, the polarity of the oscilloscope output will simply be reversed. The discharge from the defibrillator is transferred to the QA-45's load resistance.
4. Select **CHARGE TIME (F3)** from the main menu and the charge button on the defibrillator simultaneously.



When the defibrillator is charged, discharge it through the instrument.

5. Charging time will be shown in the display as 'Chrg T: xx.x MS' under RESULT.

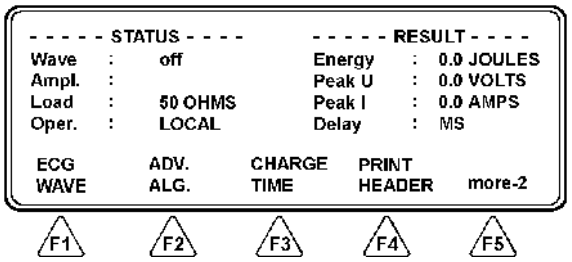


4.6 Shock Advisory Algorithm Test

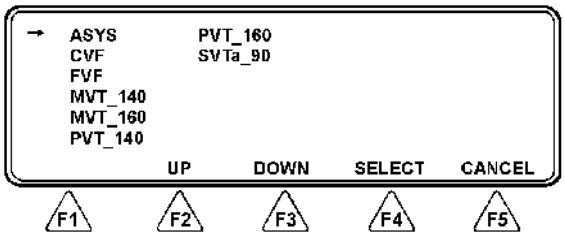
1. This tests the analysis and prompting of automatic and semi-automatic defibrillators. A series of arrhythmia is available for analysis by the defibrillator that should then prompt the user to 'shock' of 'no shock,' in accordance with national and international guidelines, as shown below:

ASYS	No shock
SVTa_90	No shock
PVT_140	No shock
MVT_140	No shock
CVF	Shock
FVF	Shock
PVT_160	Shock
MVT_160	Shock

2. Select **ADV. ALG. (F2)** from the main menu.



3. The Advisory Algorithms Menu opens.



Select the desired rhythm by pressing **UP (F2) or DOWN (F3)**. Save this under 'Wave" in the STATUS field by pressing **Select**. Press **CANCEL (F5)** to cancel selection. The ECG signal is output through the low-level ECG connectors, high-level ECG connector, and paddle contact plates on the QA-45.

4. Set the defibrillator to analyze the ECG rhythm and operate in the automatic and semi-automatic mode.
5. Records the defibrillator's response.

5. Transcutaneous Pacemaker Mode Testing

This chapter explains QA-45 transcutaneous, or pacer mode testing,

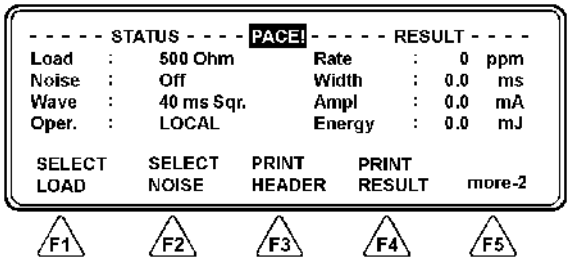
5.1 Introduction

QA-45 tests all types of transthoracic pacemakers. The testing is menu driven, and simple to operate. QA-45 measures and displays a pacer pulse's amplitude, rate, energy and width. It also conducts demand sensitivity tests, measuring and displaying refractory periods, and immunity tests, which determine the pacemaker's susceptibility to 50/60 Hz interference.

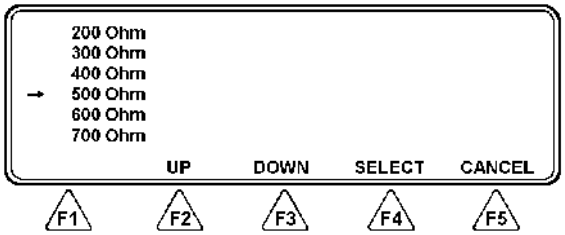
5.2 Testing Preparation

1. Connect the pacer output cables to the pacer input connectors.
2. Switch the mode switch to 'PACE' mode.
3. Turn the QA-45 on. The following will be displayed in the LCD display for about two seconds:

4. The following main menu will then appear:


- - - - - STATUS - - - - PACE! - - - - - RESULT - - - -
Load : 500 Ohm Rate : 0 ppm
Noise : Off Width : 0.0 ms
Wave : 40 ms Sqr. Ampl : 0.0 mA
Oper. : LOCAL Energy : 0.0 mJ
SELECT LOAD
SELECT NOISE
PRINT HEADER
PRINT RESULT
more-2
F1
F2
F3
F4
F5

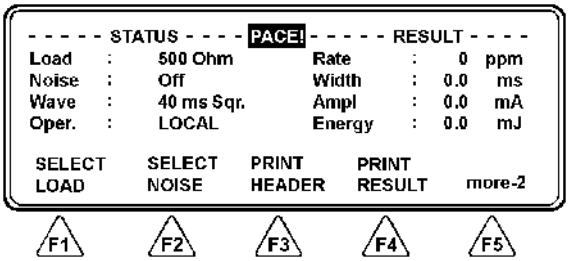
5. Press **SELECT LOAD (F1)**. The following load options will appear:



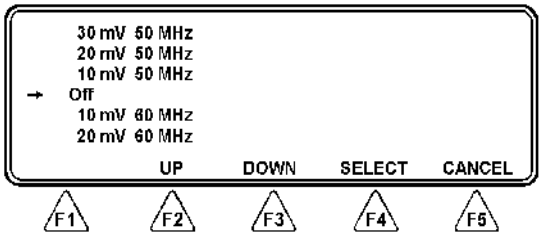
The load range is 50 to 2300 ohms in steps of 50 ohms up to 200 ohms, and 100 ohms from 200 up to 2300 ohms

Select the desired noise form by pressing **UP (F2) or DOWN (F3)** and then **Select (F4)**. Press **CANCEL (F5)** to cancel the selection. After selection the main menu will reappear.

6. Select the desired waveform by pressing **UP (F2) or DOWN (F3)** and then **SELECT (F4)**. Press **CANCEL (F5)** to cancel the selection. After selection the main menu will reappear.



7. **For Immunity Testing Only**. The immunity test determines the pacemaker's susceptibility to 50/60 Hz interference signals. If you desire to test immunity simultaneously with other testing, press **SELECT NOISE (F2)**. The following load options will appear:



Select the desired noise form by pressing **UP (F2) or DOWN (F3)** and then **SELECT (F4)**. Press **CANCEL (F5)** to cancel the selection. After selection the main menu will reappear.

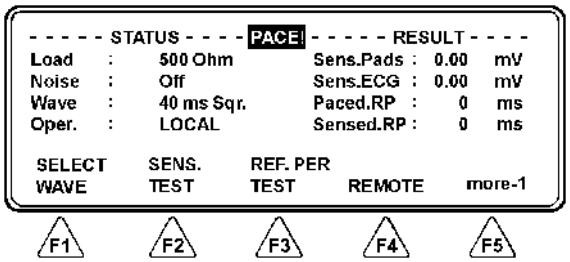
5.3 Demand Sensitivity Test

1. **General.** Sensitivity is the minimum QRS amplitude (mV) required to cause the pacemaker to operate in the demand mode. During sensitivity measurement three different waveforms are selectable with widths varying in steps from 10 to 200 ms. This waveform is delayed from the pacer pulse so that it is outside the pacing refractory period. QA-45 then checks whether this wave is sensed or not by the pacemaker.

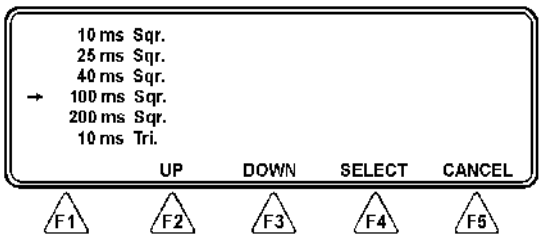
   If it is not sensed, a message 'exceeded' is displayed which means that the pacemaker needs an amplitude more than 100 mV for sensing at that setting. If the wave is sensed, QA-45 then reduces the amplitude in steps until it reaches the lowest value required for the pacemaker to sense it. (The internal algorithm used converges to the lowest value in the least number of cycles.) This lowest value is the sensitivity.

2. **Procedure**

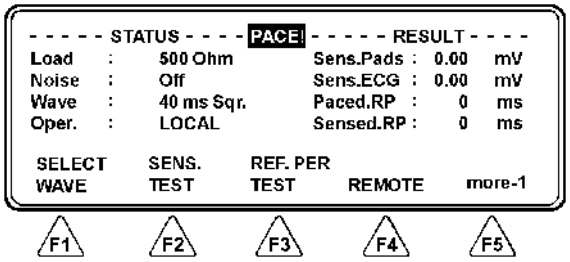
   a. From the main menu press **more-2**, then **SELECT WAVE (F1)**.


- - - - - STATUS - - - - PACE! - - - - - RESULT - - - -
Load : 500 Ohm Sens.Pads : 0.00 mV
Noise : Off Sens.ECG : 0.00 mV
Wave : 40 ms Sqr. Paced.RP : 0 ms
Oper. : LOCAL Sensed.RP : 0 ms
SELECT WAVE
SENS. TEST
REF. PER TEST
REMOTE
more-1
F1
F2
F3
F4
F5

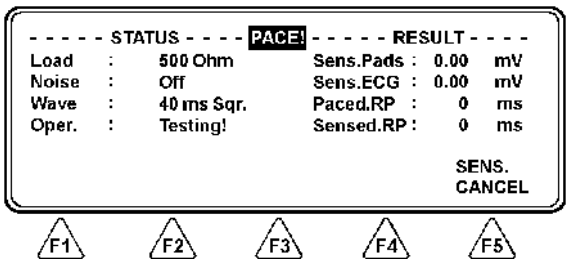
b. The following menu will be displayed:



c. Select the desired waveform by pressing **UP (F2)** or **DOWN (F3)** and then **Select (F4)**. Press **CANCEL (F5)** to cancel the selection. After selection the main menu will reappear.



d. Select **SENS. TEST (F2)**. The following display will appear:



e. Upon completion of testing the results will be displayed under RESULT. Press **SENS. TEST. CANCEL (F5)** to cancel the test.

5.4 Refractory Period Test

1. **General.** This test is used to test the time interval in milliseconds (ms) during which the pacemaker is insensitive to any external inputs. QA-45 does this by measuring the maximum time interval after the generation of a pacer pulse, and maximum time interval after a QRS wave.

   a. **Refractory Period**. A time interval in milliseconds, during which a pacemaker is insensitive to any external inputs. If a QRS is detected during this period, the pacemaker ignores it. On the other hand, if a QRS is detected outside the refractory interval, then the pacemaker resets its internal

timer and the next pacer pulse is generated after a delay of one time period from this QRS wave.

b. **Paced Refractory Period.** The maximum time interval after the generation of a pacer pulse during which time the presence of a QRS wave is ignored.

The measurement of paced refractory period takes a few cycles of the pacemaker output. First, QA-45 measures the pacer-to-pacer interval T. Then, it puts out a square wave 40 milliseconds wide, delayed by delay time D, which is more than the pacing refractory period, from the last pacer pulse. The pacemaker senses this square wave. The delay time D is gradually decremented in subsequent cycles until the square waveform is not sensed by the pacemaker. The maximum value of the delay time D, for which the pace maker does not sense the square wave, is the paced refractory period.

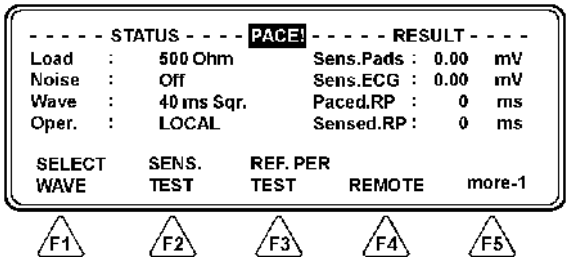
c. **Sensed Refractory Period.** The maximum time interval after a QRS wave is sensed by the pacemaker during which time the presence of a second QRS wave is ignored.

The sensed refractory period is measured in a similar manner, except that QA-45 now generates two square waves instead of one. The first square wave is generated at a fixed time delay from a pacer pulse, which is greater than the paced refractory period. The pacemaker always senses this square wave.

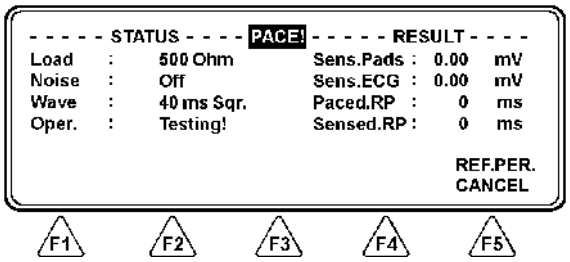
The second square wave is generated at a delay D from the first square wave. The initial value of D is selected to be greater than the sensed refractory period. Therefore the first time the pacemaker is on it also senses the second square wave. In subsequent cycles, the delay 'D' is gradually reduced until the pacemaker is unable to sense the second square wave. The maximum value of D, for which the pacemaker does not sense the second square wave, is the sensed refractory period.

2. **Procedure**

a. From the main menu press **more-2**. Press **REF. PER. TEST (F3)**.



b. The following display will appear while testing:



c. Upon completion of testing the results will be displayed under RESULT. Press **REF. PER. CANCEL (F5)** to cancel the test.

This page intentionally left blank.

6. Control and Calibration

This chapter explains the QA-45 maintenance procedures, including testing and calibration.

6.1 Required Test Equipment

- Digital multimeter, 10 uV resolution, 0.1% accuracy.
- Frequency counter
- Oscilloscope
- Variable VIA power supply
- 10 V (+0.01 v) power source
- Pulse generator: square pulse, 10 ms width, 10V amplitude, 80 pulses per. minutes (for pacer module).

6.2 Preparation

Set the switches on QA-45 to the following positions:

Mode: Low
Power: Off

Connect a power supply to the battery eliminator input on QA-45. Adjust the power supply to 9V (±0.2v) with a power limitation of 200 mA (±50 mA).

6.3 References

The function keys are numbered 1 to 5, with switch 1 farthest to left.

6.4 Test

1. Set power to ON. Wait 3 seconds, and measure the current from the power supply. Requirement: 68 mA (±5 mA).
2. Adjust P2 on the processor board to obtain the best possible contrast on the display. The display should show the main menu and the result with 0-data. Press function switch 5 and check that QA-45 changes between various menus. Adjust P103 out of limit.
3. Set power to OFF, and then back to ON after about 1 second. The display should show the software version number for a brief period, before showing the main active display. (By test under production a additional item shall be used.)
4. Measure the operating voltages in QA-45 with the multimeter. The following values are acceptable:

Test point -	Test point +	Level	Maximum Deviation

TP8 - TP6	+8.8V	±0.2V
TP8 - TP4	-8.0V	±0.3V
TP8 - TP2	+2.5V	±0.075V
TP8 - TP5	-8V	+2 -1V
TP8 - TP3	+5V	±0.1V

5. Connect the frequency counter to TP7 and read the frequency.

   Requirement: 2 MHz (±0.002 MHz).

6. Slowly reduce the voltage from the power supply until the instant the display gives the message: 'Change battery, and reset system'. Measure the operating voltage with the multimeter.
   Requirement: 6.9V (±0.3v). Return the operating voltage to 9.0V. and reset QA-45 by switching off the power for a short period.

7. Select 80 BPM in the ECG Wave Menu. Connect the oscilloscope to TP1 for signal, and TP8 to ground. Check that QA-45 generates a 80 BPM signal with an amplitude of approximately 250 mV on the R pulse. Connect the oscilloscope to the High Level ECG contact and check that the same signal is present, only with an amplitude of approximately 1V on the R pulse.

8. Set power to OFF. Measure the resistance from the RL output to the RA, LA and LL outputs.

   Requirement: 1000 ohm (±30 ohm).

9. Measure the resistance from the RL output to the V2, V3, V4, V5 and V6 outputs.

   Requirement: 1000 ohm (±30 ohm).

10. Set power to ON and go into the **SYSTEM TEST (F1)** of the page 3 menu and choose ECG + by moving the cursor and pressing **SELECT (F4)**. Measure and adjust the voltage between TP1 and TP8 to 0.490V ±1 mV. Choose ECG 0 from menu. Measure the voltage between TP1 and TP8 and check that it is between +20 mV and -10 mV.

11. Choose ECG + from the System Test Menu, measure the voltages between the ECG outputs, and check that they fall within the limits shown in the following table:

Contact	Power limit	Nom. Value	Upper limit
RL - RA	1.20 mV	1.35 mV	1.50 mV
RL - LA	2.40 mV	2.65 mV	2.90 mV
RL - LL	3.00 mV	3.35 mV	3.70 mV
RL - V1	2.70 mV	3.02 mV	3.30 mV
RL - V2	3.30 mV	3.72 mV	4.10 mV
RL -V3	4.00 mV	4.49 mV	5.00 mV
RL - V4	4.50 mV	5.06 mV	5.60 mV
RL- V5	4.00 mV	4.49 mV	5.00 mV
RL - V6	3.30 mV	3.72 mV	4.10 mV

12. Measure the voltage at the High ECG output.

    Requirement: 2.0V (±0.05v).

13. Measure and check that the voltage between the defibrillator pads is 2 mV ±50 µV. Choose ECG - by moving the cursor and pressing **SELECT (F4)**. Measure and check that the voltage between the defibrillator pads is -2 mV ±50 µV.

14. Set the power to Off, and wait 10 seconds. Measure and note the exact value of the resistance between the defibrillator pads.

    Requirement: 50 ohm (±0.5 ohm).

    Set the power switch to ON while simultaneously holding down function key 1, until the main menu appears. The main menu will now be quickly replaced by the menu for calibrating resistance. Adjust two measurement values by pressing + and -. The values will be stored in QA-45's EEPROM when SAVE & QUIT is pressed.

15. Set the power switch to Off. Remove the covers at J106 and J107. Measure the resistance between TP101 and TP102.

    Requirement: 2 MOhm (±2 kOhm).

    Repeat the measurement for TP103 and TP104.

16. Replace the covers at J106 and J107. Check that the Mode switch is set to Low. Measure the resistance between TP102 and TP105.

    Requirement: 2 kOhm (±2 ohm).

    Measure the resistance between TP108 and TP100.

    Requirement: 2 kOhm (±2 ohm).

17. Set the Mode switch to High. Measure the resistance between TP102 and TP106.

    Requirement 10 kOhm (±10 ohm).

    Measure the resistance between TP109 and TP100.

    Requirement 10 kOhm (±10 ohm).

18. Measure the resistance between TP102 and TP113.

    Requirement: 200 kOhm (±200 ohm).

    Measure the resistance between TPl14 and TP100.

    Requirement: 200 kOhm (±200 ohm).

19. Measure the resistance between TP102 and TP107.

    Requirement 10 kOhm (±10 ohm).

    Measure the resistance between TP104 and TP110.

    Requirement 10 kOhm (±10 ohm).

20. Set power switch to ON. Connect a frequency counter to pin 3 on IC106 and measure the frequency.

    Requirement: 1.9 MHz (±200 kHz).

21. Measure the voltage between TPl12 and TP100. Adjust P104 until the voltage is 5V (±0.0005v).

22. Go to the System Test Menu and choose A/D-read by moving the cursor and pressing **SELECT (F4)**. The input voltage at the A/D converter should be displayed on the screen. The value is updated once every second. Adjust P103 until the value is as close to 0 as possible.

23. Connect a 10V (±0.01v) power source between TP107 and TP110. Check that the Mode switch is set to High. Adjust P102 until the displayed value is 1997.5 mV and 2000 mV. Change the polarity on the power source and re-measure the voltage. Adjust P102 and P103 until the value displayed is between 1997.5 and 2000 mV regardless of the polarity status. Check that the scope output is +2000 mV (±20 mV) or -2000 mV (±20 mV). Remove the power source and secure P102, P103 and P104. Switch Off the power.

24. Connect a printer to the printer port. Switch on the power. heck that the Mode switch is set to High. Go to the System Test Menu and activate **TEST PULSE (F1)**. Check that QA-45 gives a correct printout, that the energy measurement on the display and printer is 125 Joules (±20 %), and that the measured voltage is approx. 2500 V. Set the Mode switch to Low and activate **TEST PULSE (F1)**. Check that the measured energy value is approx. 5 Joules (±20 %), and that the measured voltage is approx. 500V.

25. Connect a PC to the serial port and try to control QA-45 remotely. Check that communication functions in both directions.

26. Go to the System Test Menu and choose ECG +. (Last setting for pacer should be default setting: 500 ohm). Measure the voltages In pacer module with the multimeter. The following values are acceptable:

Test point - +	Level	Maximum Deviation
TP1 - TP5	-2.378V	±23 mV
TP1 - TP6	+2.378V	±23 mV

27. Connect a 10V (±0.01v) power source to the pacer input. (Last setting for pacer should be default setting: 500 ohm). Measure the voltages on pacer module with the multimeter. The following values are acceptable:

Test point - +	Level	Maximum Deviation
TP1 - TP2	+61.04 mV	±625 µV
TP1 - TP3	+244.1 mV	±2.5 mV
TP1 - TP4	+0.9766 V	±10 mV

28. Go out of the System Test Menu and choose pacer program with the slide switch. Go to the **SELECT LOAD (F1)** and choose 50 ohm. Connect a ohm meter to the pacer input and measure the resistance for all load settings. The following values are acceptable:

Nominal	Min. value	Max. value
50 ohm	49.5 ohm	50.5 ohm
100 ohm	99 ohm	101 ohm
150 ohm	148.5 ohm	151.5 ohm
200 ohm	198 ohm	202 ohm
300 ohm	297 ohm	303 ohm
400 ohm	396 ohm	404 ohm
500 ohm	495 ohm	505 ohm
600 ohm	594 ohm	606 ohm
700 ohm	693 ohm	707 ohm
800 ohm	792 ohm	808 ohm
900 ohm	892 ohm	909 ohm
1000 ohm	990 ohm	1010 ohm
1100 ohm	1089 ohm	1111 ohm
1200 ohm	1188 ohm	1212 ohm
1300 ohm	1287 ohm	1313 ohm
1400 ohm	1379 ohm	1421 ohm
1500 ohm	1478 ohm	1522 ohm
1600 ohm	1576 ohm	1624 ohm
1700 ohm	1675 ohm	1725 ohm
1800 ohm	.1773 ohm	1827 ohm
1900 ohm	1872 ohm	1928 ohm
2000 ohm	1970 ohm	2030 ohm
2100 ohm	2069 ohm	2131 ohm
2200 ohm	2167 ohm	2233 ohm
2300 ohm	2266 ohm	2335 ohm
Open (43.78 ohm)	43.649 ohm	43.911 ohm

29. Set the pacer load to 50 ohm. Connect a pulse generator to the pacer input. Check that the measured values: (If the pulse generator not handle 10V amplitude in 50 ohm, you must scale the values).

Parameter	Value	Max. Deviation
Rate:	80 ppm	±0.5 ppm
Width:	10 ms	±0.3 ms
Amplitude:	200 mA	±1.5 mA
Energy:	20.0 mJ	±2.0 mJ

30. Set the pacer load to 500 ohm. Connect a pulse generator to the pacer input. The following values are acceptable:

Parameter	Value	Max. Deviation
Rate:	80 ppm	±0.5 ppm
Width:	10 ms	±0.3 ms
Amplitude:	20 mA	±1 mA
Energy:	2.0 mJ	±0.5 mJ

31. Set the pacer load to 1000 ohm. Connect a pulse generator to the pacer input. The following values are acceptable:

Parameter	Value	Max. Deviation
Rate:	80 ppm	±0.5 ppm
Width:	10 ms	±0.3 ms
Amplitude:	10 mA	±1 mA
Energy:	1.0 mJ	±0.5 mJ

The test is complete!

7. Component Functions and Parts

This chapter provides a detailed description of the functions of the main components of the QA-45, as well as a parts list for cross-reference.

The QA-45 is based on 4 circuit boards: a processor board, sensor board, ECG signal distribution board and pacer module. The boards are described in 12 circuit diagrams which are located in Appendix A. Diagrams 1 through 4 describe the processor board; Diagrams 5 through 8 describe the sensor board; Diagrams 9 and 10 describe the ECG distribution board, and Diagrams 11 and 12 describe the pacer module.

7.1 Theory of Operation

The QA-45 Defibrillator/Transcutaneous Pacer Analyzer is a battery powered unit, based on a microprocessor and analogue electronics with precision data acquisition circuits. Using controls on the front panel of the unit, one can analyze defibrillator and pacer pulses, when these are discharged through built-in load resistors. The unit can also generate a number of different ECG, test and stimulus signals. The measurement results appear on an LCD display, and can be output to a printer. A serial port (RS-232C) makes remote control from a PC possible. All measurement and control signals are connected via contacts on the top and rear of the unit. To operate the unit, there are 5 soft keys linked with menus on the LCD display.

7.2 Processor Board

(Refer to QA-45 Processor Board Component Location Diagram and Schematic Diagrams 1-3)

1. **Printer Output** *(Schematic Diagram 1)***.** QA-45 has a printer output with a standard 25-pin D-sub contact for Centronics® interface. The output is based on 3 HCMOS circuits: IC9, IC10 and IC11. All the circuits are connected to I/O-ports on the microprocessor. ICll is a latch for the 8 parallel data lines. IC9 is the driver for outgoing control signals, while IC10 is a buffer for incoming control signals. RP1 contains pull-up resistors for the input lines. All connections to the printer contact are filtered to reduce high frequency radiation.
2. **Serial Port** *(Schematic Diagram 1)***.** The serial port is suitable for 9-pin RS-232C format. The QA-45 is configured as DTE (data terminal equipment) and should be connected to, for example, a PC with a null-modem cable. IC6 is the driver for the data signals. All handshakes take place via software. The control signals are routed back to the contact.
3. **Curve Generator** *(Schematic Diagram 1)***.**

ECG curves are generated by the microprocessor based on data tables. The processor updates the 8-bit D/A-converter in IC1 (channel A), usually 500 times per second. IC-3 converts current to voltage, and IC-2 makes the signal bipolar. The amplitude is adjusted using P1, and the zero point is adjusted using P4. From pin 1 on IC2 (TP-1) the stimulus signal is led via cables to resistive voltage dividers on the ECG signal distribution card.

IC1 D/A-converter part B sets the reference level for the curve generator D/A-converter part A. Part B thus determines the amplitude of the stimulus signal. The DC value for maximum amplitude is read back by the microprocessor's 10-bit A/D-input El, and can therefore be adjusted precisely.

The other half of IC2 is used for operating the high-level output for the ECG signal. The circuit has an amplification of 4 times. The signal is filtered for high frequency noise with F18 before it is conducted to contact J8. C3 ensures bandwidth limitation in IC2. D9 is over voltage protection.

4. **Power Supply** *(Schematic Diagram 2).*

The unit is powered either from 2 internal 9V batteries or from an external 9V DC power supply. The batteries are connected in parallel via J6 and J10, while the external power supply can be connected to J7. D1 protects against incorrect polarization. R16 is a PTC fuse that provides high impedance if too much power is drawn. F19 provides high-frequency filtering and protects against voltage transients from the power supply. The supply voltage is conducted to the sensor board through the power switch and back. F23 and F24 ensure reduction of high-frequency radiation from the power supply cables.

After the power switch SW108, the supply voltage is conducted to the power supply circuits. The supply voltage is also used directly as internal +9V. IC5 is a capacitive switch regulator that regulates -9V from the +9V. These voltages will alternate, and may vary from 7V to 12V.

IC4 is a series regulator that supplies the circuits with +5V. The circuit has an output that resets the micro controller when the +5V voltage falls below 4.75V. D6 and C13 provide the printer output with its own +5V. D6 will block power inflow through the printer cable when the QA-45 is switched off.

D7 and D8 rectify an AC signal from pin 2 IC-5, and build up a voltage of -18V via C29. From this voltage, IC17 generates bias voltage to the LCD display. The bias voltage is about -7V, and is adjusted using P2 to set the contrast of the display.

5. **Microprocessor** *(Schematic Diagram 3).*

The microprocessor IC13 contains the CPU, RAM, A/D-converter, parallel I/O and serial I/O. Y1 functions as a clock and

time reference for the processor. The frequency on TP7 is the crystal frequency/4 (2 MHz).

U9 is an EPROM that stores the processor's program. The circuit can store 128 Kbytes of program data. IC16 is a RAM circuit used for storage of measurement data. Together with the LCD display, these circuits are connected directly to the microprocessor's bus. IC15 is a PAL that sends chip-select signals to the EPROM, RAM and LCD display. The PAL circuit is in the base, and can be replaced if the program is updated. IC7 is a serial EEPROM that stores calibration data. Data is transferred via the processor's I/O ports.

The A/D converter in the processor is used to monitor the battery voltage. The voltage is divided by R12 and R13, and fed into the A/D converter via port E0. The Vref. voltage from IC12 *(Diagram 1)* is used as the reference for the A/D (VRH).

7.3 Sensor Board

(Refer to QA-45 Sensor Board Component Location Diagram and Schematic Diagrams 4-6)

1. **Serial Interface** *(Schematic Diagram 4).* Signal transfer between the processor board and the sensor board is in digital series form. IC108 is a serial-to-parallel converter that sends data to the signal M UX ICl14. IC112 reads parallel data from the switches used for operation. The data format is adapted to the microprocessor's SPI interface, and clocked by the SCK clock from the processor. The A/D converter IC104 (Diagram 3) has its own serial interface connected to the SPI lines.

2. **Switches For Operation** *(Schematic Diagram 4).*

   The front panel on the QA-45 has 5 push buttons and 2 sliding controls for operation. The push buttons SW101 - SW105 are soft keys to which different functions are assigned by the software. The switches are read from the processor via ICl12.

   SW108 is an On/Off switch that breaks the battery voltage *(see Diagram 2)*. SW106 *(Diagram 6)* sets the input attenuation by selecting different resistor values. The switch also has a digital connection (HI_LO and PACED signal) so that the microprocessor can read the switch position.

3. **Stimulus Output** *(Schematic Diagram 4).* IClll amplifies the stimulus signal from the processor board, and sends this differentially to the pads. R141 is connected to the range selector SW106, which provides different amplification for pacer stimuli and defibrillation stimuli.

4. **Scope Output** *(Schematic Diagram 5).* Scope output is fed with a signal from IC114, which is an analogue MUX. The signal can be selected digitally from 4 sources; the scope signal from the input amplifier for the defibrillator pads, or 3 versions (lev-

els) of the input signal from the pacer module. IC110 buffers the signal, which is fed to J109 via R129.

5. **Internal Power Supply Sensor Board** *(Schematic Diagram 5)*. IC107 regulates the -9 volt potential down to stable -5V for use in the A/D converter system. Dl14 prevents incorrect polarization and latch-up when the QA-45 is switched on and off. D108, D109 and Dl10 provide over-voltage protection.

6. **Measurement Input** *(Schematic Diagram 6)*.

   R185 and R186 together make up a 50-ohm load resistance for the discharges from the defibrillator being tested. The voltage over the resistors is conducted via IC101 and IC102 into the A/D converter IC104. This samples the voltage every 100 µs, and the measurement values are transferred digitally to the microprocessor.

   The measurement input is based on an attenuator that consists primarily of a differentially connected operational amplifier (IC101). Using SW109, the attenuation can be set as 10, 200 or 1000 times. The output signal from IC101 may fluctuate from +5 to -5 Volt. With an input attenuation of 1000, the measurement range becomes +5000 to -5000 Volt (High Range). With an input attenuation of 200, the measurement range becomes +1000 to -1000 Volt (Low Range). With an input attenuation of 10, the measurement range becomes +50 to -50V (pacer mode).

   IC102 is used as an addition amplifier. Here, the measurement signal is added to an offset signal generated by the other half of IC102, set using P103. A test signal can also be added in to test the A/D converter function. P102 adjusts the input attenuation.

7. **A/D Converter** *(Schematic Diagram 6)*. The A/D converter system consists of IC104, IC105 and, IC106. IC104 is the A/D converter itself, while IC105 is the voltage reference, and IC106 is the clock generator.

   The analogue signal is fed into the A/D converter on pin 7, and the measurement result is read serially on pins 15 to 18. The A/D has a differential input, and can function with 12- or 13-bit resolution. IC106 is a square wave oscillator that generates the clock signal to the analogue part of the A/D converter. The frequency of the signal is nominally 1.9 MHz, but may vary between 1.7 and 2.1 MHz.

   IC105 is the voltage reference for the A/D converter. P104 can be used for precise adjustment of the voltage to exactly 5 Volt (TPl12).

7.4 ECG Signal Distribution Board

(Refer to QA-45 ECG Distribution Board Component Location Diagram and Schematic Diagram 7)

Here, the stimulus signal (ECG-signal) is fed through 10 attenuators that set up the correct level for the outputs. The output impedance to earth is 500 ohm for all outputs. Filters on the outputs ensure damping of high-frequency components in the signal.

7.5 Pacer Unit

(Refer to QA-45 ECG Pacer Unit Component Location Diagram and Schematic Diagram 8)

The pacer module consists of 3 blocks. These are the resistor group, stimulus output and input amplifier.

1. **Resistor Group.** The value of the load resistance for the pacer input is set using 6 relays, which are connected over a range of resistors. The relays are controlled by U4, which in turn is controlled from the microprocessor via a serial interface. The relay configuration is determined in the software, and the relays are operated in such a way that the load resistance can be varied from 50 to 2300 ohm, with 50/100 ohm resolution. The relays are of the side stable (latching) type, and will therefore use no power from the batteries except when they are operated. Before the relays are set, they are all reset via pin 18 on U4.
2. **Stimulus Output.** The stimulus signal that is generated on the processor board is fed to U1, which, together with U2, makes up a programmable gain block. The signal is amplified with U3, and fed differentially over the load resistance via R17 and R18. As the load resistance may be varied, and R17 and R18 are constant, the amplitude out from U3 must be adapted to the load setting. This is done using the gain block (U1 and u2), which is controlled from the microprocessor via the same serial interface as U4.
3. **Input Amplifier.** The input signal is measured over the load resistor with the differential amplifier U5. The measurement signal is fed to the A/D converter's MUX from the output on U5. U6 contains 2 amplifiers that each have a gain of 4 times (12 dB). The outputs from these amplifiers are also added to the A/D converter MUX, so that one can choose between 3 different dynamic measurement ranges. The measurement ranges are selected according to the load setting.

7.6 Component Parts

COMPONENT PART	TYPE/VALUE	QTY.	DIAGRAM REFERENCE
PROCESSOR BOARD			
Processor board	AR-095	1	
Microprocessor	MC68HC11G5FN	1	IC13
RAM	LH5160HD-10L	1	IC16
EPROM	27C010-120	1	IC14
EEPROM	X24C16P	1	IC7
PAL	PAL. 22V10Z-25PC	1	IC15
D/A converter	MX7528KN	1	IC1
Op.amp	LM358P	1	IC17
Op.amp	LT1013DN8	2	IC2, IC3
V-ref.	LM-385Z-2V5	2	IC12, IC18
Timer	LMC555CN	1	IC106
Port	74HC05N	1	IC9
Bus driver	74HC541N	1	IC10
Latch	74HC573N	1	ICll
Volt. Regulator	LP2951CN	1	IC4
Volt. Converter	LT1054CN8	1	IC5
IC base	20 pin DIL	1	IC1
IC base	20 pin SIL	1	IC14
IC base	24 pin 300mil	1	IC15
IC base	84 pin PLCC	1	IC13
LCD display	DMF5005N	1	
Diode	1N4148	2	D2,D5
Schottky diode	1N5819	2	D4, D6
Schottky diode	BAT54	2	D7, D8
Zener diode	13V	1	D1
Transzorbdiode	BZW06-6V4B	1	D3
Transzorbdiode	BZW06-17B	3	D9 - Dll
Crystal	8 MHz	1	Y1
Resistor	1K0 1% 0.5W	1	R8
Resistor	2K2 1% 0.5W	1	R9
Resistor	3K3 1% 0.5W	1	R13
Resistor	10K 1% 0.5W	3	R6, R10, Rll
Resistor	18K 1% 0.5W	1	R19
Resistor	22K 1% 0.5W	1	R12
Resistor	30K 1% 0.5W	1	R7
Resistor	40K 1% 0.5W	1	R1
Resistor	47K 1% 0.5W	3	R5, R14, R18
Resistor	80K 1% 0.5W	2	R3, R4
Resistor	10M 1% 0.5W	1	R2
Resistor	OR	1	L4
PTC resistor	MF-R030 Boums	1	R16
Potentiometer	50K 1-turn	1	P2
Potentiometer	10K 20 turn	1	P1
Resistor pack	5 x 2K2	1	RP3
Resistor pack	8 x 4K7	1	RP4
Resistor pack	8 x 10K	2	RP1, RP2
Cer. capacitor	22pF 50V	2	C1, C2
Multilay. X7R	lnF 50V	1	C3
Multilay. X7R	4n7 50V	1	C4
Multilay. X7R	100nF 50V	9	C6 - Cll, C15, C16, C19
Electrolyte Capacitor	10µF 16V	1	C13
Electrolyte Capacitor	100µF 16V	6	C18, C23 - C27
Electrolyte Capacitor	10µF 30V	1	C28 - C30
RF coil	1.2mH	2	L2, L3

COMPONENT PART	TYPE/VALUE	QTY.	DIAGRAM REFERENCE
EMI Filter	DSS306-91Y	28	F1-F18, F21, F22, F25 - F31
EMI Filter	DSS710-D22	1	F19
EMI Filter	DSS306-91F	9	F20, F23, F24, F32 - F34, F37 - F38
Battery contact	FemaleS-G9312#0	1	J7
Header	2 pole	2	J6, J10
Phono-base	CLIFF PHS2A	1	J8
D-sub	9p Male 90 degrees	1	J2
D-sub	28p Female 90 degrees	1	J1
Flat cable terminal	26P	2	J35, JII
Flat cable plug	16P	1	
Flat cable plug	20P	1	
Box header	20P	1	J9
Connector	36-pol	1	TP101 -TP9
Flat cable	16 leads 280 mm		
Flat cable	25 leads 200 mm		
SENSOR BOARD			
Sensor board	AR-082	1	
Volt. regulator	MAX664CPA	1	IC107
A/D converter	LTC1290CCN	1	IC104
Op.amp	TL1413CN8	3	IC102, ICI10, ICIII
Op.amp	LT1012ACN8	1	IC101
V-ref.	LT1027CCN8-5	1	IC105
Timer	LMC555CN	1	IC106
Shift register	74HC589AN	1	ICI12
Shift register	74HC595AN	1	IC108
NAND port	74HC00AN	1	ICI13
Multiplexer	74HC4052P	1	ICI14
Diode	1N4148	3	DIII - DI13
Zener diode	5V1	4	D104 - D107
Schottky diode	1N5819	1	DI14
Transzorb diode	BZW06-10B	2	D101, D102
Transzorb diode	BZW06-17B	3	D108 - DI10
Resistor	47R 1% 0.5W	1	R184
Resistor	100R 1% 0.5W	1	R192
Resistor	499R 1% 0.5W	3	R131, R138, R139
Resistor	1K0 1% 0.5W	1	R129
Resistor	2K0 0.1% 0.5W	2	R121, R124
Resistor	3K16 0.1% 0.5W	1	R140
Resistor	3K3 1% 0.5W	1	R132
Resistor	3K74 1% 0.5W	1	R130
Resistor	3K9 0.1% 0.5W	16	R1245-R151, R153 - R159, R180, R181
Resistor	4K7 0.1% 0.5W	1	R141
Resistor	5K36 1% 0.5W	2	R188, R193
Resistor	8K06 1% 0.5W	1	R109, RI18
Resistor	10K 0.1% 0.5W	4	R122, R123, R125, R126
Resistor	10K 1% 0.5W	5	R128,R136,R137,R143,R190
Resistor	20K 0.1% 0.5W	3	R127, R142, R144
Resistor	20K 1% 0.5W	1	R135
Resistor	40K2 1% 0.5W	1	R134
Resistor	90K9 1% 0.5W	1	R191
Resistor	180K 1% 0.5W	2	R133, R189
Resistor	200K 0.1% 0.5W	2	R120, R187
Resistor	249K 0.1% 0.5W	16	R101 - R108, RI10 - RI17
Resistor	10M 1% 0.5W	3	R194 - R196
Resistor	0R	2	L102, L103
Resistor	N.C.	1	RI19
Power resistor	25R 1%	2	R185, R186
Potentiometer	1K 20-turn	1	P102

COMPONENT PART	TYPE/VALUE	QTY.	DIAGRAM REFERENCE
Potentiometer	10K 20 turn	2	P103, P104
Resistor pack	8 x 10K	1	RP101
Cer. capacitor	220pF 50V	1	C102
Cer. capacitor	470pF 50V	1	C101
Multilay. X7R	10nF 50V	1	CI13
Multilay. X7R	100nF 50V	11	C104-CI12, CI16, C120
Multilay. X7R	470nF 50V	1	C114
Electrolyte Capacitor	100µF 25V	1	C103
Tantal	10µF 25V	4	C115, CI17-C119
RF coil	1.2mH	1	L101
EMI Filter	DSS306-91Y	1	F101
Sliding switch	4P3T	1	SW106
Sliding switch	4PDT	1	SW108
Pressure switch	15.501	5	SW101 - SW105
Switch top	16.300.09	5	
KK contact	2 pole pin	2	J102, J109
KK contact	2 pole house	3	
Pin for KK		6	
BNC base		1	
Solder washer for BNC base		1	
Cable	120 mm		
Cable	230 mm		
Base	16 pin	1	J101
Spacer	M3x5 nylon	4	
Screw	M3x12 nylon	4	
Nut	M3 nylon	4	
ECG SIGNAL DISTR. BOARD			
ECG signal distr. circuit board	AR-094	1	
Resistor	499R 1% 0.5W	10	R2, R3, R5, R7, R9, RII, R13, R15, R17, R19
Resistor	47K5 1% 0.5W	1	R14
Resistor	53K6 1% 0.5W	2	R12, R16
Resistor	64K9 1% 0.5W	2	R10, R18
Resistor	72K3 1% 0.5W	1	R6
Resistor	80K6 1% 0.5W	1	R8
Resistor	90K9 1% 0.5W	1	R4
Resistor	180K 1% 0.5W	1	R1
N.C.			D1
EMI Filter	2n2 DSS306	10	F1 - F10
KK contact		1	J1
KK contact	house	2	J1
Pin for KK		4	J1
Connector	36-pol	2	TP1, TP2
Cable	1L+Sk 120 mm		
PACER UNIT			
Pacer circuit board	PCB1 AR-081	1	
D/A converter	DAC8043FP	1	U1
Op.amp	LT1413CN8	2	U2, U3
Op.amp	LT1012ACN8	1	U5
Op.amp	LT1112CN8	1	U6
Relay driver	UCN5842A	1	U4
Resistor	7R5 1% 0.5W	1	R32
Resistor	49R9 0.1% 0.5W	2	RII, R7
Resistor	100R 0.1% 0.5W	1	R2
Resistor	420R 0.1% 0.5W	2	R3, R30
Resistor	820R 0.1% 0.5W	3	R4, R5, R31
Resistor	820R 1% 0.5W	3	R22, R33, R34
Resistor	1690R 0.1% 0.5W	1	R6

COMPONENT PART	TYPE/VALUE	QTY.	DIAGRAM REFERENCE
Resistor	1K52 0.1% 0.5W	2	R21, R22
Resistor	1K8 1% 0.5W	1	R12
Resistor	2K 0.1% 0.5W	1	Rll
Resistor	10K 0.1% 0.5W	4	R9, R13, R,?.5, R28
Resistor	10K 1% 0.5W	3	R15, R24, R27
Resistor	20K 0.1% 0.5W	4	R8, R10, R14, R16
Resistor	24K 0.1% 0.5W	2	R17, R18
Resistor	30K 0.1% 0.5W	2	R26, R29
Resistor	249K 0.1% 0.5W	2	R19, R20
Multilay. X7R	100nF 50V	8	C1 - C5, C7, C8, C10
Electrolyte Capacitor	100µF 25V	1	C9
N.C.			C6
RF coil	1.2mH	1	L1
Relay	-B201	4	K1 - K4
Relay	-B101	2	K5, K6
Connector	2x36-pol	1	J1
KK contact	4-pol	1	J4
Connector	36-pol	1	TP1 -TP6

This page intentionally left blank.

Appendix A - Diagrams

Processor Board Component Location Diagram.....A-2

Schematic Diagram Part 1 (Processor Board).....A-3

Schematic Diagram Part 2 (Processor Board).....A-4

Schematic Diagram Part 3 (Processor Board).....A-5

Sensor Board Component Location Diagram.....A-6

Schematic Diagram Part 4 (Sensor Board).....A-7

Schematic Diagram Part 5 (Sensor Board).....A-8

Schematic Diagram Part 6 (Sensor Board).....A-9

ECG Signal Distribution Board Component Location Diagram.....A-10

Schematic Diagram Part 7 (ECG Signal Distribution Board).....A-11

Pacer Unit Component Location Diagram.....A-12

Schematic Diagram Part 8 (Pacer Unit).....A-13

USA
1345 Monroe NW, Suite 255A
Grand Rapids, MI 49505
Phone: (+1) 888 863-8766
Fax: (+1) 616 454-3350
E-mail: support.us@metron-biomed.com

FRANCE
30, rue Paul Claudel
91000 Evry, France
Phone: (+33) 1 6078 8899
Fax: (+33) 1 6078 6839
E-mail: info@metron.fr

NORWAY
Travbaneveien 1
N-7044 Trondheim, Norway
Phone: (+47) 7382 8500
Fax: (+47) 7391 7009
E-mail: support@metron.no

From: (name) _____ Phone: _____
Address: _____ Fax: _____
_____ E-mail: _____
_____ Date: _____

Error Report

Product: Version: Serial no.:

Description of the situation prior to the error:

Description of the error:

(METRON AS internally)

Comments:

Received date:	Correction date:	Ref No.	☐ Critical ☐ Normal ☐ Minor

USA
1345 Monroe NW, Suite 255A
Grand Rapids, MI 49505
Phone: (+1) 888 863-8766
Fax: (+1) 616 454-3350
E-mail: support.us@metron-biomed.com

FRANCE
30, rue Paul Claudel
91000 Evry, France
Phone: (+33) 1 6078 8899
Fax: (+33) 1 6078 6839
E-mail: info@metron.fr

NORWAY
Travbaneveien 1
N-7044 Trondheim, Norway
Phone: (+47) 7382 8500
Fax: (+47) 7391 7009
E-mail: support@metron.no

METRON

From: (name)		Phone:	
Address:		Fax:	
		E-mail:	
		Date:	

Improvement Suggestion

Product: _____ Version: _____

Description of the suggested improvement:

(METRON AS internally)

Comments:

Received date:	Correction date:	Ref No.	☐ Critical ☐ Normal ☐ Minor

USA
1345 Monroe NW, Suite 255A
Grand Rapids, MI 49505
Phone: (+1) 888 863-8766
Fax: (+1) 616 454-3350
E-mail: *support.us@metron-biomed.com*

FRANCE
30, rue Paul Claudel
91000 Evry, France
Phone: (+33) 1 6078 8899
Fax: (+33) 1 6078 6839
E-mail: *info@metron.fr*

NORWAY
Travbaneveien 1
N-7044 Trondheim, Norway
Phone: (+47) 7382 8500
Fax: (+47) 7391 7009
E-mail: *support@metron.no*

METRON